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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/484,542	06/07/95	BRADER	M X-10097
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BANNER & ALLEGRETTI LTD  
ELEVENTH FLOOR  
1001 G STREET NW  
WASHINGTON DC 20001-4597

HM11/0219

EXAMINER

ALLEN, M

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

02/19/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**08/484,542**

Applicant(s)  
**Brader et al.**

Examiner  
**Marianne Allen**

Group Art Unit  
**1645**



☒ Responsive to communication(s) filed on Dec 29, 1997

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-12, 25, and 26 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-3, 9-12, 25, and 26 is/are rejected.

☒ Claim(s) 4-8 is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1645

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1645.

Claims 1-12 and 25-26 are under consideration by the examiner.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments with respect to claims 1-12 and 25-26 have been considered but are moot in view of the new ground(s) of rejection.

The properly executed declaration filed on 29 December 1997 under 37 CFR 1.131 is sufficient to overcome the Havelund et al. reference. The rejections based upon this reference are hereby withdrawn.

The disclosure is objected to because of the following informalities: Claim 3 contains a typographical error, "humin."

Appropriate correction is required.

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Claims 2, 5-6, and 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 lacks a terminal period (“.”).

It appears that claim 5 should refer to a concentration of a phenolic compound (“per milliliter”) to be consistent with claim 2.

Claim 25 is confusing in reciting “fortified.” It is unclear what specific limitation other than the presence of zinc this term is intended to impart.

Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Baker et al. (U.S. Patent No. 5,693,609) (of record).

Baker et al. discloses an aqueous formulation of an acylated insulin where zinc is present in the amount of 0.7% (encompassed by the claims as indicated on page 8, lines 12-15). Phenol is present at 30 mM (encompassed by the range set forth in the claim when converted to the corresponding units). (See column 9, lines 10-20.) This formulation is administered to dogs. (See column 9.) The reference is silent as to the pH of the formulation administered. However, absent evidence to the contrary, pharmaceutical formulations are usually administered at or near physiological pH which would be within the range set forth in the claims.

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Claims 3 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. (U.S. Patent No. 5,693,609).

Baker et al. is applied as above and further teaches that a preferred acylated insulin is B29-N<sup>ε</sup>-Asp<sup>B28</sup>-palmitoyl human insulin (B29 is acylated). (See column 5, lines 62-63.).

With respect to claims 9-12, the reference further suggests that the formulations may contain mixtures of unacylated insulin or insulin analog in the range of 1:99 to 99:1. (See column 8, lines 48-58.) Thus, it would have been obvious to include either normal insulin (unacylated) or an insulin analog in the formulation disclosed by Baker et al.

With respect to claim 3, it would have been obvious to substitute the preferred acylated insulin B29-N<sup>ε</sup>-Asp<sup>B28</sup>-palmitoyl human insulin (B29 is acylated) in formulation 1 (see column 9) in order to administer it to dogs. One would have been motivated to do so to evaluate its pharmaceutical properties.

Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. (U.S. Patent No. 5,693,609) in view of the specification at page 7.

Baker et al. discloses an aqueous formulation of an acylated insulin where zinc is present in the amount of 0.7% (encompassed by the claims as indicated on page 8, lines 12-15). (See column 9 lines 10-20.) The reference does not disclose lyophilization of the formulation.

One of ordinary skill in the art would have known that such aqueous preparations were routinely lyophilized in order to perform purity and structural analyses or lyophilized so that the

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aqueous solution could be reconstituted later for administration. As indicated in the specification at page 7, the techniques of lyophilization and reconstitution would have been well known.

Therefore, it would have been obvious to lyophilize the aqueous solution taught by Baker et al.


The Baker et al. reference does not anticipate nor fairly suggest a solution containing 0.3 to 0.55 mole of zinc per mole of fatty acid-acylated insulin.

Claims 4-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, Ph.D., can be reached on (703) 308-4310. Official FAX communications may be directed to either (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
MARIANNE P. ALLEN  
PRIMARY EXAMINER  
GROUP 1800